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Psychometric assessment of the Italian version of the melanoma module (SCNS-M12-Ita) of the Supportive Care Needs Survey (SCNS-SF34)

Miniotti Marco[1], Zeneli Anita[2], Bassino Stefania[1], Pavan Sara[1], Ribero Simone[3] and Leombruni Paolo[1]

Abstract

Introduction: This study examines the validity and the reliability of the translated-into-Italian version of the SCNS-SF34 melanoma module (SCNS-M12-Ita) for a sample of patients with melanoma ($n = 268$).

Methods: Content validity was analyzed by examining the redundancy of items. Floor/ceiling effects were investigated via frequency tables. Factor structure was studied through principal component analysis. Internal consistency was evaluated with Cronbach α. Test–retest reliability was analyzed using intraclass correlation coefficients (ICCs). Convergent–discriminant validity was studied by calculating Pearson correlations. Construct validity was investigated by comparing subgroups of patients through multivariate analysis of variance.

Results: Content validity of the SCNS-M12-Ita was satisfactory. The floor effect ranged from 24.3% to 82.5%. The 2-factor solution explained 61.4% of the total variance. Internal consistency was excellent for component 1 ($\alpha = 0.92$) and questionable ($\alpha = 0.58$) for component 2. Test–retest reliability was excellent for component 1 (ICC = 0.92) and poor for component 2 (ICC = 0.58). Except for component 2, item-total correlations were greater than 0.60. Construct validity was confirmed, as the expected correlations ($r < 0.40$) were observed and 60% of the postulated hypotheses about between-group differences were confirmed.

Conclusions: The study demonstrated that the SCNS-M12-Ita is a valid and reliable instrument for assessing the supportive care needs of patients with melanoma.

Keywords

Supportive Care Needs Survey, supportive care needs, melanoma, psycho-oncology, psychometrics, assessment

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Introduction

As patients with cancer encounter challenges in every area of life over the course of the disease, precise assessment of perceived needs is essential to tailoring the provided health-care in order to meet each patient's supportive care needs.[1] To tailor intervention most effectively, patient-reported outcomes (PROs) are recognized as accurate measures that facilitate patient-centered care in oncology.[2] PROs are scientifically designed, developed, and tested instruments based on a report obtained directly from patients on the self-perceived status of their health conditions without amendment or interpretation of responses by a clinician or anyone else.[2] Common types of PROs are self-report rating scales or surveys assessing patients' experience of disease- and treatment-related symptoms, including quality of life components, psychological distress, psychosocial burden,

[1]"Rita Levi Montalcini" Department of Neuroscience, University of Turin ~~15~~, Turin, Italy
[2]Istituto Scientifico R[illegible]nolo per lo Studio e la Cura dei Tumori (IRST), IRCCS 40, Meldola (FC), Italy
[3]Department of Medical Sciences, De[illegible]logic Clinic, University of Turin, Turin, Italy

Corresponding author:
Marco Miniotti, "Rita Levi Montalcini" Department of Neuroscience, University of Turin 15, Via Cherasco, Turin 10126, Italy.
Email: marco.miniotti@unito.it

and satisfaction with care.[2] Assessing these parameters yields a list of problems and concerns that do not indicate what patients actually feel they need help with. Moreover, an assessment of symptoms and functioning alone is insufficient for obtaining a comprehensive picture of a patient's condition, as such an assessment does not provide an indication of the extent to which the problems affect the patient.[3] In contrast, needs assessment directly identifies specific aspects of patients' needs and quantifies the perceived magnitudes of such needs, enabling individuals and subgroups of patients to be identified and targeted with appropriate interventions.[3] Research has confirmed the unique importance of needs assessment; despite indicated significant associations among functioning, symptoms, and needs,[4] studies have also recognized poor agreement among these aspects when the level of functioning was low.[5]

Among the various instruments available to assess the supportive care needs of patients with cancer,[6] one of the most comprehensive (with respect to health status and satisfaction with care), valid, and reliable tools is the Supportive Care Needs Survey (SCNS).[7] The original long form of the SCNS (SCNS-LF59) was derived from the Cancer Needs Questionnaire and consisted of 59 items.[7] To enhance its practical utility, further psychometric development of the tool has led the authors to release a short form called the SCNS-SF34.[8] The 34 items of the SCNS-SF34 assess specific cancer-related perceived needs across 5 factors of analytically derived domains that are identical to those of the longer version: psychological (10 items), health system and information (11 items), physical and daily living (5 items), patient care and support (5 items), and sexuality (3 items).[8,9] A validation study on a large heterogeneous sample of patients with cancer showed that the 5-factor structure of the SCNS-SF34 accounts for 73% of the total variance; the model was supported by confirmatory factor analysis.[8,9] SCNS-SF34 also demonstrated excellent internal reliability (Cronbach α from 0.87 to 0.97) and high internal consistency (Cronbach α from 0.86 to 0.96).[8,9] Supplementary modules providing detailed information on needs specific to the cancer site have been developed for use in conjunction with SCNS-SF34.[9] Currently, modules for breast, head and neck, and prostate cancers, melanoma, and colostomy are available.[9] Scoring for the SCNS-SF34 and supplementary modules is performed on a 5-point Likert scale, where patients indicate if they have a need and the extent of the need (1 = "no need, not applicable"; 2 = "no need, satisfied"; 3 = "low need"; 4 = "moderate need"; 5 = "high need"). To date, the SCNS-SF34 has been translated into Italian, French, German, Dutch, Japanese, and Chinese.[10–15]

The SCNS melanoma module (SCNS-M12) is applicable to a wide range of patients with melanoma, varying in stage, treatment, and time since diagnosis. It consists of 12 items assessing needs related to skin soreness, recurrence, and information on treatment and skin protection. The module takes approximately 6 minutes to complete.[9,16] The SCNS-M12 has not been validated psychometrically and has not been translated into Italian.

With the growing impact of melanoma on healthcare worldwide, particularly in Europe, where despite the expenditures-related disparities in prognosis across the continent,[17] prevention is generally lower and incidence rates are increasing,[18,19] the assessment of the supportive care needs of patients with melanoma is essential. Identifying specific issues that patients need help with (without any assumptions from the clinicians about patients' care requirements) and directly quantifying the urgency of the need for help enables care to be focused on the issues patients have recognized as needing help with the most.[9] On a broader scale, needs assessment might enable service providers to prioritize resources in enhancing the aspects of care that need to be improved.[8,9]

In view of the growing interest in the application of needs assessment to cancer care, this study aims to assess content validity, factor structure, convergent and discriminant validity, construct validity, internal consistency, and reproducibility of the translated-into-Italian version of the SCNS-M12 (SCNS-M12-Ita).

Methods

This study was performed at the Dermatologic Surgery of the Oncology and Hematology Department at the Città della Salute e della Scienza University Hospital in Turin, Italy. The study was performed in accordance with the principles of the Declaration of Helsinki and was approved by the internal ethics committee.

Participants and procedures

Patients diagnosed with primary cutaneous melanoma in the TIS-T3 clinical stages were considered eligible for this study. All patients were approached at least 6 months after treatment. Exclusion criteria included being younger than 18 years and being physically or mentally unable to provide written informed consent and/or complete written questionnaires. Patients were approached in person in the waiting room. After being ascertained to be eligible, patients gave their informed consent and were asked to complete a defined set of self-report scales and questionnaires in a reserved room after having been fully informed of the methods and purposes of the study. There were no specific time limits for completing scales and questionnaires, which took approximately 30 minutes. A second administration of the SCNS-M12-Ita to evaluate its reproducibility was performed by mail within 2 weeks after the first assessment session, and completed questionnaires were mailed back by the patients using preaddressed and prestamped envelopes. One reminder via a telephone call was provided if the questionnaire was not returned on time.

Instruments

Patients were asked to complete the translated-into-Italian version of the SCNS supplementary module for melanoma (SCNS-M12-Ita), the Hospital Anxiety and Depression Scale (HADS), the Distress Thermometer (DT), and the 36-item Short Form Health Survey (SF-36).

The SCNS-M12 is a supplementary module of the SCNS-SF34 specifically developed to assess the perceived supportive care needs related to having melanoma. It consists of 12 items related to skin soreness, lymphedema, risk of recurrence, pain, information on treatments, skin changes, and skin protection.[9,16]

The HADS is a self-rated scale for assessing anxiety and depression. It consists of 14 items and yields scores on 2 independent subscales measuring symptoms of anxiety (HADS-A) and depression (HADS-D). For each subscale, scores of 8–10 are considered borderline, while those above 11 suggest clinical anxiety or depression.[20]

The DT assesses psychological distress. It is a one-item self-report screening tool for measuring psychological distress over the last week using a thermometer-like scale with scores from 0 (no distress) to 10 (extreme distress). A cutoff score of 4 has been identified and generally accepted as the best balance between sensitivity and specificity.[21]

The SF-36 assesses quality of life. It consists of 36 questions exploring 8 health domains: physical functioning, physical role functioning (role limitations due to physical health), bodily pain, general health, vitality, social functioning, emotional role functioning (role limitations due to emotional problems), and mental health.[22]

Statistical analyses

Data were analyzed using SPSS software v 20.0 (IBM, Armonk, NY). Content validity was analyzed by examining the redundancy of items. Items were considered redundant if fewer than 10% of the patients reported a need. Exploratory factor analysis (EFA) was performed to examine whether the single items of the SCNS-M12-Ita could be aggregated into a more limited set of multi-item scales. Principal component analysis (PCA) with varimax rotation was performed. The Kaiser-Meyer-Olkin (KMO) measure of sample adequacy and the Bartlett test of sphericity were calculated to test the appropriateness of the sample size. Factors were identified using the Kaiser-Guttmann criterion (eigenvalues $\geqslant 1$). Test–retest reliability was analyzed using intraclass correlation coefficients (ICC). An ICC value of 0.70 or above was considered satisfactory. Convergent–discriminant validity was studied by calculating the Pearson product moment correlations between SCNS-M12-Ita items and the HADS, SF-36, and DT subscales. It was expected that subscales that were conceptually related (e.g. the SCNS-M12 item addressing the need to be informed about the necessity for surgical removal of lymph nodes and HADS-A) would significantly correlate with each other (Pearson r being greater than 0.40). A Pearson r of less than 0.40 was considered to be an indicator of weak correlation, values in the range from 0.40 to 0.60 indicated a moderate correlation, and an r greater than 0.60 signified a strong correlation. Conversely, subscales that had little in common with each other (e.g. the SCNS-M12 item addressing the need to access and consider a second opinion regarding treatment and condition and the SF-36 bodily pain subscale) were expected to show low correlations (Pearson r less than 0.40). Construct validity of SCNS-M12-Ita was studied by comparing the scores between groups of patients according to specific hypotheses based on the literature. It was postulated that patients who were younger,[23] were female,[12] were more recently diagnosed,[24] had symptoms of anxiety and depression,[23] and underwent sentinel lymph dissection[23,25] would report higher levels of needs. A comparison of scores between subgroups of patients using a multivariate analysis of variance (MANOVA), with Cohen standardized effect size (η^2) as an estimate of the magnitude of the differences and an α set at 0.01, was performed to test the discriminant validity of the SCNS-M12-Ita. The Scheffé method was used as a post hoc test to address unequal group sizes. Floor or ceiling effects (having over 15% of patients with the lowest or the highest possible score) were investigated using frequency tables.

Results

Patient characteristics

A total of 350 patients with primary cutaneous melanoma were invited to participate in this study. Of these, 79 (22.6%) refused to participate, and 3 (0.9%) did not provide analyzable forms. A total of 268 patients took part in the study. Respondents and nonrespondents did not differ significantly in any demographic or medical aspect. Demographic and medical characteristics of the participants are summarized in Table 1.

Content validity

Except for item 1, "skin soreness," and item 2, "lymphedema (swelling of a limb after gland dissection)," at least 20% of patients reported a met or unmet need on all SCNS-M12-Ita items.

Floor and ceiling effects

In this study, the floor effect corresponded to having no need for care. Floor effects ranged from 24.3% (item 8) to 82.5% (item 1). No ceiling effects were present (Table 2).

Table 1. Sample characteristics.

	No. (%)
Age, y	
⩽49	95 (35.4)
50–59	68 (25.4)
60–69	68 (25.4)
⩾70	37 (13.8)
Sex	
Male	127 (47.4)
Female	141 (52.6)
Marital status	
Married/in partnership	190 (70.9)
Single/widowed	78 (29.1)
Age at leaving school, y	
⩽11	19 (7.1)
12–14	66 (24.6)
15–19	127 (47.4)
⩾20	56 (20.9)
Current employment	
Paid employment	134 (50.0)
Not working	49 (18.3)
Retired	85 (33.2)
Time since diagnosis, mo	
⩽24	133 (49.6)
25–49	46 (17.2)
⩾50	89 (33.2)
Surgical procedure	
Wide local excision	112 (41.8)
SLNB (negative result)	132 (49.3)
Lymph node dissection	24 (9.0)
Stage of melanoma	
TIS	28 (10.4)
T1a	96 (35.8)
T1b	48 (17.9)
T2a	32 (11.9)
T2b	17 (6.3)
T3	47 (17.5)
Breslow thickness, mm	
⩽1	153 (57.1)
1.01–2	55 (20.3)
2.01–4	30 (11.2)
>4	30 (11.2)
Anatomical site	
Head and neck	18 (6.7)
Trunk	126 (47.0)
Upper limb	37 (13.8)
Lower limb	87 (32.5)

SLNB: sentinel lymph node biopsy.

Factor structure of the SCNS-M12

The KMO measure was 0.911 and the Bartlett test was significant ($\chi^2 = 1711.02$, $p < 0.0001$). The EFA identified 2 components defined by the Kaiser-Guttman criterion, explaining together 61.4% of the total variance. Component 1 comprised 10 items related to the need for specific information on melanoma and explained 50.5% of the variance. Component 2 comprised 2 items related to lymph swelling and skin soreness after gland dissection and explained 10.9% of the variance. Factor loadings and communalities for the 2-factor solution along with the coefficient α for the 2 components are presented in Table 2.

Reliability

The internal consistency of the SCNS-M12-Ita was excellent for component 1 (Cronbach $\alpha = 0.919$) and questionable for component 2 (Cronbach $\alpha = 0.582$; Spearman-Brown coefficient of 0.583). The test–retest reliability was excellent for component 1 (ICC = 0.919) and poor for component 2 (ICC = 0.582). Item-total correlations were above 0.60 except for item 1 (0.37) and item 2 (0.30) of component 2.

Convergent–discriminant validity

None of the SCNS-M12-Ita items correlated highly with DT, HADS, or SF-36 subscales (Table 3). Significant weak correlations were observed among items 5, 8, and 11 (that investigate the need for more information regarding the surgical treatment and skin protection) and depression, bodily pain, physical functioning, and mental health.

Construct validity

Contrary to our assumptions, a MANOVA using Pillai trace showed no significant effect of age ($V = 0.014$, $p = 0.747$, $\eta^2 = 0.007$) or sex ($V = 0.006$, $p = 0.488$, $\eta^2 = 0.006$) on the SCNS-M12-Ita scores. In contrast, a significant effect was observed for time since diagnosis ($V = 0.047$, $p = 0.015$, $\eta^2 = 0.024$), surgical procedure ($V = 0.177$, $p < 0.001$, $\eta^2 = 0.088$), and presence of anxiety and depression ($V = 0.046$, $p = 0.002$, $\eta^2 = 0.046$), confirming our assumptions. Patients with a significant amount of time elapsed since diagnosis (⩾50 months) reported higher needs on component 1 ($p = 0.009$) than patients with a more recent diagnosis (⩽24 months). Patients who had undergone lymph node dissection reported higher needs on component 1 than those who had negative sentinel lymph node biopsy ($p < 0.001$) and those who had undergone wide local excision ($p < 0.001$). Patients who showed borderline or clinical levels of anxiety and depression reported higher needs on component 1 ($p = 0.002$) than those who had normal levels. Therefore, considering the expected between-groups differences, 3 of the 5 hypotheses (60%) were confirmed. Descriptive statistics for significant group differences are shown in Table 4.

Table 2. Floor and ceiling effects of the SCNS-M12 and the identified factor structure in patients with melanoma ($n = 268$).

SCNS-M12 item	Percentages of scores		Factor loadings		h^2
	Low	High	C1	C2	
8. To be informed about things you can do for skin protection	24.3	7.8	0.836	−0.106	0.711
9. To be informed about how and when to check for skin changes	24.6	10.4	0.819	−0.005	0.670
7.More information about possible outcomes when melanoma has spread from the skin	42.2	9.7	0.764	0.268	0.719
4. To be informed about the need of surgical treatment of melanoma of the skin	35.4	3.7	0.742	0.265	0.621
6. More information about nonsurgical treatment of melanoma (chemotherapy, immunotherapy)	60.8	5.2	0.728	0.230	0.583
11. More information about the unwanted effects of surgical treatment	54.1	7.1	0.723	0.289	0.616
3. More information about the risk of recurrence of melanoma	33.6	6.0	0.722	0.206	0.564
10. Access to a second opinion about your condition or treatment if you want one	60.4	4.5	0.704	0.100	0.496
5.To be informed about the need for surgical removal of lymph nodes	48.1	4.9	0.693	0.301	0.571
12.Information about how to control pain	57.8	6.7	0.64	0.223	0.524
2.Lymphedema (swelling of a limb after gland dissection)	72.4	2.6	0.07	0.794	0.636
1. Skin soreness	82.5	3.7	0.159	0.79	0.652
Variance			50.5	10.9	
Cronbach α			0.92	0.58	

C1: component 1; C2: component 2; h^2: communalities; SCNS-M12: Supportive Care Needs Survey melanoma module.

Table 3. Correlations of SCNS-M12 items and HADS, DT, and SF-36.

SCNS-M12 item	Ha	Hd	DT	SFv	SFpf	SFbp	SFghp	SFprf	SFerf	SFsrf	SFmh
1	0.12	0.13	0.02	−0.14	−0.06	−0.07	−0.26[a]	−0.04	−0.13	−0.12	−0.09
2	0.13	0.08	0.02	−0.04	−0.16	−0.03	−0.21	−0.15	−0.05	−0.08	−0.14
3	0.17[a]	0.07	0.16[a]	−0.20	−0.16	−0.13	−0.15	−0.01	−0.03	−0.06	−0.19
4	0.12	0.17[a]	0.14	−0.25[a]	−0.13	−0.19	−0.14	−0.02	−0.06	−0.18	−0.22[a]
5	0.23[a]	0.18	0.13	−0.31[a]	−0.16	−0.13	−0.35[a]	−0.20	−0.33[a]	−0.32[a]	−0.28[a]
6	0.12	0.13	0.10	−0.19	−0.15	−0.09	−0.28[a]	−0.08	−0.19	−0.33[a]	−0.25[a]
7	0.16[a]	0.19[a]	0.17[a]	−0.31[a]	−0.18	−0.15	−0.31[a]	−0.14	−0.07	−0.23[a]	−0.27[a]
8	0.15[a]	0.13	0.11	−0.30[a]	−0.19	−0.35[a]	−0.27[a]	−0.12	−0.17	−0.29[a]	−0.38[a]
9	0.17[a]	0.06	0.09	−0.25[a]	−0.19	−0.20	−0.24[a]	−0.09	−0.07	−0.20	−0.29[a]
10	0.08	0.05	0.03	−0.05	−0.01	−0.01	−0.12	−0.17	−0.12	−0.12	−0.18
11	0.10	0.20[a]	0.14	−0.32[a]	−0.35[a]	−0.21[a]	−0.28[a]	−0.25	−0.16	−0.24[a]	−0.24[a]
12	0.19[a]	0.09	0.13	−0.24[a]	−0.22[a]	−0.15	−0.32[a]	−0.10	−0.09	−0.27[a]	−0.25[a]

$r < 0.40$ indicates weak correlation.
[a]Significant correlations.
Ha: HADS–anxiety; HADS: Hospital Anxiety and Depression Scale; Hd: HADS–depression; DT: Distress Thermometer; SF-36: 36-item Short Form Health Survey; SFv: SF-36 vitality; SFpf: SF-36 physical functioning; SFbp: SF-36 bodily pain; SFghp: SF-36 general health perception; SFprf: SF-36 physical role functioning; SFerf: SF-36 emotional role functioning; SFsrf: SF-36 social role functioning; SFmh: SF-36 mental health; SCNS-M12: Supportive Care Needs Survey melanoma module.

Discussion

The SCNS-SF34 is a well-established self-report questionnaire with proven psychometric properties and recognized as a valid PRO instrument for measuring the types and extent of perceived needs of cancer patients.[8,9] The psychometric validity and reliability of this tool were also ascertained by cross-cultural studies.[10,14] More recently, several cross-cultural validation studies were also performed for supplementary modules of the SCNS-SF34. For instance, the breast module was validated in French[11] and the head and neck module was validated in Dutch.[13] To extend the previous data on the psychometric properties of the SCNS-SF34 supplementary modules and to the fill the gap in the assessment of supportive care needs of Italian patients with melanoma, this study focused on the examination of

Table 4. Differences in SCNS-M12 scores between different patient groups.

Characteristics	*V*, *p* value	SCNS-M12, mean (SD)	
		Component 1	Component 2
Age, y	0.731		
⩽49		24.3 (20.8)	1.8 (3.0)
50–59		25.9 (25.2)	1.2 (2.4)
60–69		26.2 (21.7)	1.9 (3.8)
⩾70		24.4 (23.4)	2.1 (3.3)
Sex	0.488		
Male		23.4 (21.4)	7.9 (15.0)
Female		26.8 (23.3)	8.9 (16.3)
Time since diagnosis, mo	0.146		
⩽24		28.6 (25.5)	8.9 (14.4)
25–49		26.8 (20.4)	11.5 (20.2)
⩾50		18.8 (22.5)	5.8 (13.9)
Surgical procedure	0.004[a]		
Wide local excision		22.5 (19.6)	5.0 (10.3)
SLNB (negative result)		22.1 (19.2)	10.3 (17.4)
Lymph node dissection		50.6 (30.5)	13.0 (21.5)
Anxiety/depression	0.002[a]		
Normal		21.1 (20.5)	8.5 (15.8)
Borderline to clinical		30.5 (23.9)	8.4 (15.6)

V denotes Pillai trace multivariate test; SCNS-M12 scores are standardized.
[a]Significant *p* values.
SCNS-M12: Supportive Care Needs Survey melanoma module; SLNB: sentinel lymph node biopsy.

the validity and reliability of the translated-into-Italian version of the SCNS-SF34 melanoma module (SCNS-M12-Ita) in a sample of patients with primary cutaneous melanoma ($n = 268$). Factor structure, content validity, convergent and discriminant validity, construct validity, internal consistency, and reproducibility of the SCNS-M12-Ita were subsequently assessed.

This study is the first to investigate the psychometric properties of the Italian version of the SCNS-M12. The results show overall satisfactory psychometric properties of the SCNS-M12-Ita administered to Italian patients with primary cutaneous melanoma. The instrument proved to be acceptable to patients, with a high completion rate of almost 80%. Respondents and nonrespondents did not differ significantly in any demographic or medical aspect. According to previous research,[11,13] this result also suggests that the supplementary module for melanoma of the SCNS-SF34 is easy to administer and well-accepted among patients with melanoma.

Content validity analysis of the SCNS-M12-Ita showed that the instrument did not contain redundant items. Item 1, "skin soreness," and item 2, "lymphedema (swelling of a limb after gland dissection)," belonging to component 2 identified by the EFA, did not exceed this threshold. However, we do not consider this finding surprising and those items redundant, as they address needs that are specific to the few patients (9% of the sample) who have undergone lymph node dissection.

The appropriateness of the SCNS-M12-Ita was further supported by the identified 2-factor structure. The KMO measure of sampling adequacy and the Bartlett test of sphericity confirmed the appropriateness of the data gathered in this study to perform the EFA. The PCA of the SCNS-M12-Ita revealed 2 components: component 1, which comprised 10 items on needs related to a perceived lack of information on melanoma prevention, treatments, and outcomes, and component 2, which comprised 2 items regarding lymph swelling and skin soreness after gland dissection. This factor solution explained 61.4% of the total variance, with the variables being well defined, as indicated by moderate communality values. Considering reliability, internal consistency proved to be excellent for component 1 (Cronbach $\alpha = 0.919$) and questionable for component 2 (Cronbach $\alpha = 0.582$). The somewhat low value observed for component 2 can be explained by the fact that the component contains only 2 items. The ICCs and item-total correlations also reflected this result. Test–retest reliability was excellent for component 1 (ICC = 0.919) and rather poor for component 2 (ICC = 0.582) whereas item-total correlations were all above 0.60, except for item 1 (0.37) and item 2 (0.30) of component 2. It is generally recognized that, even if correct reliability estimates (e.g. the Spearman-Brown coefficient) are reported, a 2-item dimension is generally recognized as less reliable and thereby less stable and a less valid

construct than a domain with more items that lead to better construct representation.[26]

Construct validity of SCNS-M12-Ita was studied by assessing convergent–discriminant validity by Pearson product moment correlations between its items and the HADS, SF-36, and DT subscales. In general, the expected correlations were observed; they were significant in most cases, and their observed direction was as hypothesized. However, the magnitude of the observed correlations was lower than the validity threshold of 0.40 defined a priori in all cases. These findings strengthen the results observed in previous studies[12,13] and suggest that psychological distress, symptoms of anxiety and depression, and aspects of quality of life only partially overlap with supportive care needs related to having melanoma and that such needs might therefore also be influenced by a variety of other factors according to the specificity of the disease and the personal circumstances of the patients with the disease. Construct validity of the SCNS-M12-Ita was also ascertained by evaluating its ability to discriminate between different groups of patients. Specific hypotheses were postulated based on the literature, and of the 5 assumptions made a priori, 3 (60%) were confirmed by the analyses. Patients did not differ from each other on SCNS-M12-Ita scores based on age or sex. This result confirms a recent study performed on patients with head and neck cancer aimed to assess the psychometric properties of the newly developed head and neck cancer module of the SCNS-SF34 (SCNS-HNC)[13]; however, it contradicts earlier studies that observed strong evidence of such differences.[11,12,14,15] A possible explanation for the absence of differences in supportive care needs with age and sex could be found in the high floor effect, which ranged from 24.3% to 82.5% in this study. At least 6 months had elapsed since treatment for all patients included in this study, and, in general, these patients perceived low levels of supportive care needs. This general flattening down of the SCNS-M12-Ita scores may be responsible for the limited variation in outcomes, and, consequently, in limited differences between groups. Another possible explanation may be that not all the hypotheses postulated for group differences were based on studies performed on patients with melanoma.[12,24] For instance, the hypothesized sex differences were based on a study that involved patients with heterogeneous tumor entities. The other hypothesized group differences observed in this study confirm previous research findings[23–25] and indicate that supportive care needs were influenced by a variety of individual variables other than demographic ones, including disease- and treatment-related factors, anxiety, and depression. Moreover, these findings ascertain the discriminative construct validity of the SCNS-M12-Ita.

This study has limitations. A significant amount of time had elapsed since treatment for all included patients; this factor might not only cause a floor effect on the SCNS-M12-Ita scores but also limit generalizability to patients with melanoma undergoing treatment or those with a recent diagnosis. Moreover, patients were not asked to critically review whether or not the SCNS-M12-Ita items were adequately understood and in fact considered relevant for the construct the items were intended to measure. Finally, the sample size is small. On the other hand, the primary strength of this study is the assessment of a wide range of psychometric characteristics of the SCNS-M12-Ita, including the factor structure, content validity, convergent and discriminant validity, construct validity, internal consistency, and reproducibility.

Conclusion

This study demonstrated that the SCNS-M12-Ita represents a useful, valid, and reliable PRO able to evaluate supportive care needs of patients with melanoma and discriminate between different subgroups of patients; thus it also proves to be a sensitive tool. Further research on validation of the SCNS-M12 in other populations, including patients with advanced melanoma and those undergoing treatment, is needed and encouraged.

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Declaration of conflicting interest

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ORCID iD

Miniotti Marco https://orcid.org/0000-0002-7310-5706

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